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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,390	07/31/2003	Ping Gao	01260/2/US	2821
26648	7590	09/18/2006	EXAMINER	
PHARMACIA CORPORATION GLOBAL PATENT DEPARTMENT POST OFFICE BOX 1027 ST. LOUIS, MO 63006			KISHORE, GOLLAMUDI S	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 09/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/633,390	Applicant(s) GAO ET AL.	
	Examiner Gollamudi S. Kishore, Ph.D	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2006.
 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
 4a) Of the above claim(s) 32 and 33 is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 1-31 and 34 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12-11-03</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election without traverse of Group I in the reply filed on 7-14-06 is acknowledged.

Upon consideration, the various species election requirement is withdrawn.

Claims included in the prosecution are 1-31 and 34.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 3-8, 11, 13-20, 22-31 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Block (6,440,967) in combination with Tanida (6,214,378).

Block discloses COX-2 inhibitor compositions in gelatin capsules (see col. 1, lines 20-63 and example 3 of Hancock; col. 8, line 1 through col. 15, line 12, Example 5 of Block). Block in addition teaches the inclusion of surfactants such as sorbitan monooleate, polyethylene glycol and additives such as sucrose, magnesium stearate and water (col. 18, lines 24-38).

Block however, does not teach the inclusion of an amino acid, a sulfite, ethanol and water.

Taneda while disclosing capsule formulations containing COX-2 inhibitors teaches the addition compounds such as sodium sulfite, basic amino acids, glycerol,

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oils, polyethylene glycol 400, ethanol, sodium didecyl sulfate (abstract, col. 3, line 56 through col. 4, line 32 and examples).

The addition of amino acids, sulfite and solvents, ethanol and water in the gelatin capsules of Block would have been obvious to one of ordinary skill in the art, with a reasonable expectation of success since the reference of Taneda shows the common practice in the art of adding these with COX-2 inhibitor formulations. In the absence of showing the criticality, the amounts of sulfite in claims 8, 10 and the solvent in claim 18, Celecoxib in 28 and the fill capacity of the capsule are deemed to be obvious parameters manipulated by an artisan to obtain the best possible results.

4. Claims 1-5, 9-11, 13-19, 22-31 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over in combination Block (6,440,967 with Adesunloye (5,874,106).

Block discloses COX-2 inhibitor compositions in gelatin capsules (col. 8, line 1 through col. 15, line 12, Example 5). Block in addition teaches the inclusion of surfactants such as sorbitan monooleate, polyethylene glycol and additives such as sucrose, magnesium stearate and water (col. 18, lines 24-38).

What is lacking in Block however, is the inclusion of amino acids.

Adesunloye teaches that the presence of certain ingredients in the filling promotes cross-linking in the gelatin shell with the passage of time and/or under stress conditions and when cross-linking occurs, the gelatin shell becomes less soluble in aqueous media especially in acidic aqueous media. According to Adesunloye, material which promote cross-linking in the capsule shell include carbonyl compounds, such as ketones and aldehydes and amino acids act as carbonyl scavenger, especially a

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formaldehyde scavenger. Therefore, Adesunloye advocates the inclusion of amino acids and carboxylic acids such as ascorbic acid and fumaric acid in the formulations (abstract, col. 1, line 17 through col. 4, line 8, col. 4, line 58 through col. 5, line 4 and Examples).

It would have been obvious to one of ordinary skill in the art to include an amino acid and a carboxylic acid such as ascorbic or fumaric acid in the teachings of Block since Adesunloye teaches such an inclusion would prevent the cross-linking of the gelatin capsules. Although Adesunloye does not teach amines it would have been obvious to one of ordinary skill in the art to use amines such as ethanolamine or diethylamine instead of amino acids with a reasonable expectation of a reaction with formaldehyde to prevent cross linking since both have an amine function. In the absence of showing the criticality, the amounts of sulfite in claims 8, 10 and the solvent in claim 18, Celecoxib in 28 and the fill capacity of the capsule are deemed to be obvious parameters manipulated by an artisan to obtain the best possible results.

5. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over in combination Block (6,440,967 with Adesunloye (5,874,106) as set forth above, further in view of Burch (2002/0107259).

The teachings of Block and Adesunloye have been discussed above. What is lacking in Block and Adesunloye is the inclusion of benzyl alcohol. Such an inclusion however, would have been obvious to one of ordinary skill in the art with a reasonable expectation of success since the reference of Burch shows that benzyl alcohol is commonly used in compositions containing COX-2 inhibitors (0070)

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6. Claims 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over in combination Block (6,440,967 with Adesunloye (5,874,106) as set forth above, further in view of Ng (6,861,068).

The teachings of Block and Adesunloye have been discussed above. what is lacking in Block and Adesunloye is the use of polyethylene glycol ether derivatives as excipients. Such a use however, would have been obvious to one of ordinary skill in the art with a reasonable expectation of success since the reference of Ng shows that these ethers are commonly used excipients in combination with COX-2 inhibitors (col. 11, line 64 through col. 12, line14 and claim 1).

7. Claims 2-3 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over in combination Block (6,440,967 with Adesunloye (5,874,106) as set forth above, further in view of either Aoki (5,470,578) or Caldwell (5,112,736).

The teachings of Block and Adesunloye have been discussed above. What is lacking in these references is the use of amines such as ethanolamine or ethylenediamine to react with formaldehyde to prevent gelatin cross-linking.

Aoki teaches ethylenediamine or the like or an amino acid such as lysine reacts with aldehyde group containing compounds to form CH₂NH group (col. 6, lines 15-20).

Caldwell while disclosing DNA cross-linked membranes teaches that ethanolamine passivates aldehyde groups (claim 14).

It would have been obvious to one of ordinary skill in the art to use amines such as ethanolamine instead of amino acids with a reasonable expectation of a reaction with formaldehyde to prevent cross linking since the references of Aoki, and Caldwell each

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teach that these amines have the capacity to react with aldehyde function. One of ordinary skill in the art would expect an inhibition of cross-linking similar to that observed by Adesunloye using amino acids.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Woodward Michael can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK